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Gerd Ascher

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NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

CHONG, YONG SOO

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



## **DETAILED ACTION**

### ***Status of the Application***

This Office Action is in response to applicant's arguments filed on 10/16/2006. Claim(s) 1 has been cancelled. Claim(s) 2-17 are pending. Claim(s) 5 has been amended. Claim(s) 6-17 have been withdrawn. Claim(s) 2-5, 18 are examined herein.

Applicant's amendments have rendered the 112 rejection moot, therefore hereby withdrawn. Applicant's arguments have been fully considered but found not persuasive. The 103(a) rejection of the last Office Action is maintained for reasons of record and repeated below for Applicant's convenience.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-5, 18 are rejected under 35 U.S.C. 103(a) as being obvious over Ferguson et al. (US Patent Application 2005/0159377 A1) in view of Egger et al. (US Patent 4,278,674).

The instant claims are directed to a method of treating *Mycobacterium tuberculosis* with pleuromutilins, specifically 1-Tiamulin.

Ferguson et al. teach that pleuromutilins possess antimicrobial activity (section 0002). Moreover, Ferguson et al. disclose that pleuromutilins have activity over a wide range of bacteria including *Mycobacterium tuberculosis* (section 0113 and 0114).

However, Ferguson et al. fail to disclose specifically 1-Tiamulin.

Egger et al. disclose a new class of pleuromutilins with antibacterial effects (abstract). A preferred pleuromutilin is 14-Desoxy-14-[(2-dimethylaminoethyl)mercaptoacetoxy]mutilin otherwise known as 1-Tiamulin (example 1).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to substitute 1-Tiamulin as taught by Egger et al. for the pleuromutilin as taught by Ferguson et al.

A person of ordinary skill in the art would have been motivated to make this substitution because: (1) both Ferguson and Egger et al. teach the use of pleuromutilin, (2) both Ferguson and Egger et al. teach the art equivalency of pleuromutilins since both are disclosed to have antimicrobial properties, (3) thus there is a reasonable expectancy of successfully treating *Mycobacterium tuberculosis* with 1-Tiamulin.

### ***Response to Arguments***

Applicant argues that the conclusion of obviousness was based on impermissible hindsight because Ferguson et al. discloses at least 45 different genus types of microorganisms which pleuromutilins have activity over. Applicant argues that Ferguson et al. simply fail to specifically teach anywhere in the reference that pleuromutilins would have, or would be expected to have, activity over *Myobacteria* in particular. Therefore, Applicant argues that the Examiner has applied improper obviousness to try rationale by trying each of the numerous possible choices until one possibly arrived at the successful result.

This is not persuasive because Ferguson et al. clearly discloses the general teaching that pleuromutilins are a class of protein synthesis inhibitors, which possess antimicrobial activity. This wide range of antimicrobial activity encompasses bacteria such as the disclosed *Mycobacterium tuberculosis*. Moreover, Egger et al. disclose a new class of pleuromutilins, for example 1-Tiamulin, with possesses antibacterial effects. Accordingly, the skilled artisan would have had a reasonable expectation of success in treating *Mycobacterium tuberculosis* with pleuromutilins, such as 1-Tiamulin.

Examiner notes that this is a typical genus/species situation. Once a *prima facie* case of obviousness is established, the burden is shifted to the Applicant for objective evidence for nonobviousness. See MPEP 2144.08.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

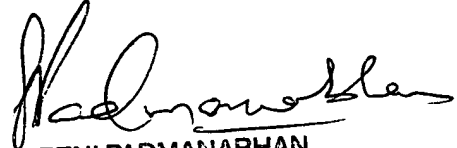
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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YSC



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER